

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Sitke AYGEN Confirmation No. 1732
Application No. 10/532,348 Art Unit 3735
Filed July 20, 2005 Examiner Navin Natnithithadha
For: METHOD FOR DETERMINING GASTRIC EMPTYING

PRE-APPEAL-BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Notice of appeal being concurrently filed, herewith, please conduct a pre-appeal-brief review of the final rejection of claims in the Office Action mailed September 17, 2010 ("final action").

Claims 3-5 were rejected under 35 USC 101 for allegedly constituting non-statutory subject matter. The rejection cannot be maintained because it relies on clear error.

Relying on *In re Bilski*, 88 USPQ 1385 (Fed. Cir. 2008) "held that method claims must pass the 'machine-or-transformation test'" to be patent eligible (final action, page 4), the rejection is made solely because "Claims 3-5 do not pass [sic] the 'machine-or-transformation test,'" which is clear error, *per se*, because the relied on holding was overturned by the U.S. Supreme Court, i.e., "The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible 'process.'" *Bilski v. Kappos*, 561 U. S. ____ (2010). As *held* by the Supreme Court, "adopting the machine-or-transformation test as the sole test for what constitutes a 'process'...violates...statutory interpretation principles." *Bilski v. Kappos*, 561 U. S. ____ (2010). Reliance on overturned, i.e., non-existing, legal precedent renders the rejection untenable (as explained, of record, in the response filed 12 July 2010).

Moreover (as explained, of record, in the response filed 9 September 2009), the rejection relies on legal standards/tests and cited precedent applied only to claims involving computer-related subject matter, even under PTO guidelines (*see* MPEP 2106.01 "Computer-Related Nonstatutory Subject Matter" (emphasis added))." Legal precedent (*Diehr, Benson, Bilski, and Flook*) cited in the rejection are mistakenly relied on since their holdings apply only to *computer-related* inventions: "*Diehr*...[involved] using a mathematical formula to complete some of its several steps by way of a computer." *Bilski v. Kappos*, 561 U. S. ____ (2010) (emphasis added). "Our recent holdings

in...*Benson*...and *Parker v. Flook*,...are computer-related." *Diamond v. Diehr*, 450 U.S. 175, 185 (1984) (emphasis added).

With all due respect, what the rejection applies is an arbitrary (i.e., user defined) machine-or-transformation test, which is no better illustrated than by the hundreds, possibly thousands, of United States patents issued since 2006 (the year the PTO decided *Ex parte Bilski*—ruled on by *In re Bilski*), having "method" claims containing the (and sometimes only) step of "administering"—typically found in pharmaceutical use (i.e., treatment) claims—characterized in the instant rejection as non-patentable "human behavior" (final action, page 5). For example, claim 11 of U.S. Pat. No. 7,875,745 is a single-administering-step method claim, i.e. (emphasis added):

A method for treatment...which comprises administering to a mammal an effective amount of the compound of formula (I).

Were the instantly applied machine-or-transformation test not arbitrary, the PTO would not have allowed and issued such hundreds (maybe thousands) of single "administering" step "method" claims, in the first place. Interestingly, "method" claims in the Ben-Oren United States patent (Primary Examiner Charles A. Marmor, II), relied on to reject the present claims under §103 (below), contain an "administering" step, and recite neither machine nor transformation.

Still further, characterizing the presently claimed method step "determining $^{13}\text{CO}_2$ content in exhaled...air" as non-patentable "mental activity" is simply *beyond the Pale* of reason: "mental activity" can in no way even detect, let alone quantify, $^{13}\text{CO}_2$. It *necessarily* requires, in practice, suitable means to measure how much $^{13}\text{CO}_2$ there is in exhaled air, such as, e.g., by IRMS (isotope ratio mass spectroscopy), as set forth, appropriately, in the instant specification, not the claims. *In re Roberts*, 176 USPQ 313, 315 (CCPA 1973) (the claims define the legal limits of the invention, the specification details *how* the invention is to be *practiced*).

For the foregoing reasons, the rejection of claims 3-5 under §101 is based on clear error and, so, reversal of the rejection of is in order.

Claim 3 was rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent 7,338,444 (Ben-Oren) in view of U.S. Patent 6,186,958 (Katzman). Claims 4 and 5 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ben-Oren in view of Katzman and further in view of GB 2360845 (Ghoos). The aforesaid rejections under §103(a) (collectively, "§103 rejections") cannot be maintained because they are based on the same clear error (explained below).

Establishing *prima facie* obviousness of a claim requires satisfaction of the *all elements rule*, i.e., all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970), and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App. 1982). A "ground of rejection is simply inadequate on its face...[when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

To satisfy the *all elements rule* (*Royka, supra*)—of both §103 rejections—the PTO relies on the combination of Ben-Oren and Katzman in the rejection of claim 3. Therefore, clear error in the rejection of claim 3 renders both §103 rejections untenable. *See In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

The rejection relies, in the alternative, on Ben-Oren or Katzman to meet the (negative) claim limitation "body-related conversion factors are dispensed with." Reliance on Ben-Oren constitutes clear error because the reference teaches the exact opposite, That is, Ben-Oren (column 16, lines 36-55) requires the use of body-related conversion factors, specifically (emphasis added)

an estimation of the CO₂ rate of production is derived from the DoB, based on the height and weight of the subject being tested....The method of obtaining the PDR and CPDR from the subject's DoB, normalized according to the subject's weight and height, is disclosed by Y. F. Ghoos et al in "Measurement of gastric emptying rate of solids by means of a carbon-labeled octanoic acid breath test", published in *Gastroenterology*, Vol. 104(6), pp. 1640-7, June 1993.

Given this requirement, Ben-Oren teaches away from the presently claimed invention, *In re Gurley*, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be...led in a direction divergent from the path that was taken by the applicant"); which, by itself, defeats the rejection. *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003) ("an applicant may rebut a *prima facie* case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect [citation omitted]").

According to the alternative reasoning in the rejection (final action, pages 5-6), "Katzman teaches the limitation 'body-related conversion factors are dispensed with' by not using them." Reliance on Katzman (allegedly) "not using them," to meet the negative claim limitation, constitutes clear error.

First, it must be recognized that Katzman does not literally teach or suggest not using "body-related conversion factors," because the reference teachings nothing about "body-related conversion

factors." While the skilled artisan would have known about body-related conversion factors, "that presumed knowledge does not grant a license to read into the prior art reference teachings that are not there." *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997). such knowledge "read into the prior art reference teachings that are not there." *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997).

Secondly, Katzman cannot be relied on as *inherently* teaching "body-related conversion factors are dispensed with." The rejection effectively alleges that, because Katzman does not teach *to* use "body-related conversion factors," the reference *inherently* teaches *not* to use them. The problem, i.e., clear error, is that the reasoning confuses (passively) omitting to teach with (actively) teaching to omit, the difference between which is recognized in the controlling legal precedent on the issue of *inherency*.

For the doctrine of *inherency* to apply the allegedly inherent claim feature must be "inevitable" from the teachings of the prior art. *In re Wilding*, 190 USPQ 59, 62 (CCPA 1976). "In relying on a theory of inherency, the Examiner must...support...that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (*emphasis original*). Before "the burden shifts," the examiner has "the initial burden of establishing a *prima facie* basis for the alleged inherency." 17 USPQ2d at 1463-64. An argument by the PTO "is not prior art," and the "mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency...[since] such a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (*emphasis added*). "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Spoormann*, 150 USPQ 449, 452 (CCPA 1966).

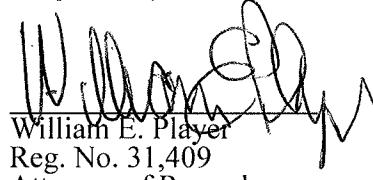
Katzman does not inherently teach the (negative) claim limitation at issue, because excluding body-related conversion factors is not "inevitable" from the teachings of the reference, *Wilding*, 190 USPQ at 62, i.e., since Katzman teaches nothing about excluding "body-related conversion factors," then including them is not proscribed and, so, excluding them cannot be *inevitable*. Accordingly, the PTO fails to meet its initial burden to "support...that the allegedly inherent [exclusion] characteristic *necessarily* flows from the teachings of the applied prior art," *Levy*, 17 USPQ2d at 1464, and reliance on Katzman constitutes an unacceptable "retrospective...substitute for some teaching or suggestion supporting [the] obviousness rejection." *Rijckaert*, 28 USPQ2d at 1957. "Obviousness cannot be

predicated on what is unknown," *Spoormann*, 150 USPQ at 452," and the "mere fact that [not using body-related conversion factors]...*may* result from [Katzman]...is not sufficient to establish inherency." *Rijckaert*, 28 USPQ2d at 1957..

Since "the cited references do not support each limitation of [each rejected] claim," as explained above, each of the §103 rejections is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. Withdrawal of the §103 rejections is in order.

Furthermore, assuming, arguendo, that Katzman did teach the exclusion of body-related conversion factors, this would be contrary to the express teachings of Ben-Oren and, so, teach away from combination with Ben-Oren, which would render the rejection untenable, in any event. *Tec Air, Inc., v. Denso Manufacturing Michigan Inc.*, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) ("There is no suggestion to combine...if a reference teaches away from its combination with another source [citation omitted]"). *Winner Int'l. Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1587 (Fed. Cir. 2000), *cert. denied*, 530 U.S. 1238 (2000) (When one reference is found to "teach away from [the other], then that finding alone can defeat the obviousness claim"). With all due respect, the PTO cannot simply ignore the fact that Ben-Oren requires the use of body-related conversion factors, it being "impermissible...to pick and choose from any one reference only so much...as will support a given position, to the exclusion of other parts necessary to...[find] what such reference fairly suggests to one of ordinary skill in the art." *In re Hedges*, 228 USPQ 685, 687 (Fed. Cir. 1986). Only by looking in the reference for what meets the claims, i.e., hindsight reconstruction, is it possible to overlook the teachings that evidence non-obviousness (explained above). "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Fine*, 5 USPQ2d at 1600.

Respectfully submitted,



William E. Player
Reg. No. 31,409
Attorney of Record

JACOBSON HOLMAN PLLC
400 Seventh Street, NW
Washington, D.C. 20004
Tel. (202) 638-6666
Fax. (202) 3935350
Date: March 2, 2011
P70555US0 pre-appeal-brief request.wpd